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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,773

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EXAMINER

UNDERDAHL, THANE E

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,773	<b>Applicant(s)</b> YONEDA ET AL.	
	<b>Examiner</b> THANE UNDERDAHL	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-10 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **Detailed Action**

This Office Action is in response to the Applicant's reply received 6/17/09. Claims 1-20 are pending. Claims 11-20 are withdrawn. No Claims are cancelled. Claims 1 and 8 have been amended. No Claims are new. Claims 1-10 are considered in this Office Action.

### **Response to Applicant's Arguments**

In the response submitted by the Applicant the 35 U.S.C § 112 First Paragraph rejection of claims 6 is withdrawn in light of Applicant's amendment Statement of Availability of the biological deposit received 5/27/09. However the rejection remains for claim 7 since no such statement was made for any mutants for *Bacillus subtilis* SD142. Also the 35 U.S.C § 103 (a) rejection of claim 1-9 over Phae et al. and supporting references is withdrawn in light of the Applicant's amendment limiting the substrate to soybean powder or defatted soybean meal and the 1.132 Declaration submitted 6/7/09. The 35 U.S.C § 103 (a) rejection of claim 1-10 over Phae et al. in view of Ohno#1 is withdrawn due to Applicant's amendment limiting the substrate to soybean powder or defatted soybean meal and the 1.132 Declaration submitted 6/7/09.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 appears to employ a mutant of *Bacillus subtilis* SD142. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 8, lines 19-25 of the specification for *Bacillus subtilis* SD142. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809 for a mutant of *Bacillus subtilis* SD142. The previous Office Action (Mailed 2/27/09, pg 3) has a list of suggestions for the deposit of biological material.

### **New Rejections Necessitated by Amendment**

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phea et al. in view of Sloma et al. (WO 98/22598) in light of support of DeMain et al. and Gary et al.

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These claims are to a method for producing **iturin A and its homologues (itAh)** comprising the following step:

- ❖ Cultivating a *Bacillus* microbe having an ability to produce **iturin A (itA)** and its homologues in a liquid medium containing 2% mass or more of soybean powder or defatted soybean powder.

The Applicant has previously argued that the limitation "wherein the microbe produces iturin A and its homologues in the medium to a concentration of 1.5 g/L or more" distinguishes the claim from the prior art. However this a "wherein clause" and is given little patentable weight since it is expressing the intended result of a positively recited active step of the method and is not itself an additional step to the method. M.P.E.P. § 2111.04 states that such a clause "in a method claim is not given weight when it simply expresses the intended result of a process step positively recited". The same applies to the "wherein clause" in claim 2. Therefore art reading on the active steps of the method also reads on the invention.

Phae et al. teach that *B. subtilis* NB22 can be fermented in no. 3 medium which is a liquid medium that contains polypepton, glucose and  $\text{KH}_2\text{PO}_4$  (Phae, pg 118, Materials and Methods) to produce and accumulate ItA (See Abstract). The polypepton concentration can be as high as 50 g/L, which is about 5% (Phae, pg 121, col 1 line 8). The amount of  $\text{KH}_2\text{PO}_4$  added to the solution was 1g/L which calculates to a %mass of 0.1% (Phae, pg 118, col 1, Materials and Methods). It is well known in the art that both  $\text{K}_2\text{HPO}_4$  and  $\text{KH}_2\text{PO}_4$  are well known nutrients for *Bacillus subtilis*, as supported by Gary et al. (pg 501, Methods) and DeMain et al. (pg 517, col 2, Mineral Salt Mixture).

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Knowing this it would be obvious to one of ordinary skill in the art to substitute  $K_2HPO_4$  for  $KH_2PO_4$  or vice versa since both are known in the art for the same purpose (M.P.E.P. § 2144.06 II).

Also Phea et al. does not teach using soybean powder for their substrate. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Sloma et al. They teach that numerous species of *Bacillus* including *Bacillus subtilis* ( Sloma, pg 6, lines 5-11) can be cultured with media containing 4% soybean flour, sucrose,  $Na_2HPO_4$  (Sloma, pg 26, lines 29-31). Therefore Sloma et al. teaches that soybean flower is an art recognized equivalent for the same purpose and it would be obvious for one of ordinary skill in the art to substitute one soybean flower into the media of Phea et al. (M.P.E.P. § 2144.06) since both were successful in culturing *Bacillus subtilis* with their respective medias. Also while the declaration of the Applicant (filed 6/17/08) shows that *B. subtilis* NB22 produces significant amounts of surfactin (Applicant's Declaration, pg 4, Results) it would be obvious to modify the *B. subtilis* NB22 to reduce the amount of surfactin it produces.

Phea et al. teaches that *B. subtilis* NB22 produces significant amounts of foam as well as Iturin A (Phae, pg 118, col 1, Introduction). Sloma et al. teach that foaming caused by *Bacillus* limits the productivity of fermentation and reduce the expression of protein (Sloma, pg 2, lines 14-25). Sloma et al. teach that modifying the *Bacillus* to produce less surfactin creates conditions conducive for the production of polypeptides (Sloma, pg 2-3 Summary of Invention). Sloma et al. teach that surfactin production for *Bacillus* can be reduced by 95% (Sloma, pg 6, lines 19-21). Using the Applicant's data

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from the 1.132 Declaration (pg 4, bottom, 710 ppm) for *B. subtilis* NB22, a 95% reduction would result in a surfactin concentration of 36 ppm in the medium, which is well below the limitation in claim 3. Sloma also teach that the polypeptides produced by the *Bacillus* can be isolated via spray drying or evaporation the culture (Sloma page 7, lines 10-15).

Therefore it would be obvious for one of ordinary skill in the art to modify the invention of Phea et al. with the teachings of Sloma et al. to produce a *B. subtilis* NB22 that reduces the amount of surfactin produced since this would achieve the common goal of expressing more polypeptides such as itAh. This would be obvious since it is using a known technique to improve on a similar method ((KSR International v. Teleflex Inc. 550 U.S. \_\_\_, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007))).

Therefore claims 1-5, 8, 9, and 10 are obvious in view of the above references.

### **Claim Objections**

Claims 6 is objected to for being dependant from a rejected claim, but is free of the art. Claim 2 is objected to because of the typo "homologs" which is inconsistent with the spelling of "homologues" used in the rest of the claims and the specification.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure**, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

#### CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached at (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl  
Art Unit 1651

/Leon B Lankford/  
Primary Examiner, Art Unit 1651